Appendix XVI.

Differences Between Deterministic and Probabilistic Risk Assessments

Deterministic Risk Assessments

The standard method used in the OPP to characterize ecological risk is the ratio or quotient method. "Typically, the ratio (or quotient) is expressed as an exposure concentration divided by an effects concentration" (U.S. EPA 1998, Part A, Section 5.1.3). A risk quotient (RQ) is the ratio of the estimated environmental concentration of a chemical to a toxicity test effect level for a given species. It is calculated by dividing an appropriate exposure estimate (e.g. EEC or estimated environmental concentration) by an appropriate toxicity test effect level (e.g. LC50). Thus, the RQ is an index (an indicator or measure of a condition) of the potential adverse effects. As an index, the risk quotient needs some reference point or bearing to have meaning. Thus, the Agency has established Levels of Concern (LOCs) in order to identify when the potential adverse effects are of concern to the Agency (see Table 1). LOCs are criteria used to indicate potential risk to non-target organisms and the need to consider regulatory action. The criteria indicate that a pesticide, when used as directed, has the potential to cause adverse effects on non-target organisms. Typically, an RQ is compared to an LOC to determine if the OPP should consider taking some regulatory action to reduce or eliminate the potential risk, or to further refine the risk assessment.

OPP first presented this risk index method in the *Standard Evaluation Procedure for Ecological Risk Assessment* in 1986 (U.S. EPA. 1986). Since the issuance of the 1992 policy by the Assistant Administrator (U.S. EPA. 1992), OPP has generally pursued ecological risk mitigation whenever RQs exceed the LOCs. Currently these RQs and LOCs are used in screening level risk assessments to express potential acute and chronic risk to birds, wild mammals, fish, aquatic invertebrates, and plants.

The current ecological risk characterization process, which is based on RQs and LOCs, is useful and can provide the risk managers with a screening method to facilitate the rapid identification of pesticides that are not likely to pose an ecological risk or those that may pose a risk. As noted in the EPA Ecological Risk Assessment Guidelines, "The principal advantages of the quotient method are that it is simple and quick to use and risk assessors and managers are familiar with its application. It provides an efficient, inexpensive means of identifying high- or low-risk situations that can allow risk management decisions to be made without the need for further information" (U.S. EPA 1998, Part A, Section 5.1.3). It also provides a "crude index of magnitude of effects and therefore can be used for comparisons among alternative compounds where comparable data are available" (Ecological Committee on FIFRA Risk Assessment Methods, 1999b, Section 5.3, page 5-11). Thus, RQs and LOCs are useful as part of an initial or screening level characterization of the ecological risk. In addition, there are a number of reasons to continue to include RQs and LOCs in OPP ecological risk assessment, including: "Quotients may serve as an interim measure that provides a bridge for risk assessors and risk managers between current and new probabilistic risk assessment methods; Quotients remain a primary method ... may continue to be used by EPA risk managers; [lacking good case studies using other methods including probability]... it is premature to eliminate deterministic quotients; Quotients may play a role in future evaluations by providing a benchmark to which new methods could be compared; Further evaluation of risk characterization methods ... may demonstrate that quotients serve a useful purpose in determining the applicability of the risk assessment and identification of scenarios of concern (e.g., during the Problem Formulation stage)" (ibid, Section 6.2, pages 6-3 and 6-4).

While the objective of EFED is to advance toward probabilistic risk assessment methods, current deterministic methods such as the quotient have not been dismissed. Rather, they remain an integral component of the current risk assessment for the registration and reregistration of pesticides. This is consistent with current Agency guidance for Ecological Risk Assessment. However, many risk assessors and risk managers who use RQs recognize that they contain an unknown degree of conservatism and they tend to obscure uncertainties and variability. Thus, while an RQ can be useful in determining whether risk is likely to be high or low, it may not be helpful to a risk manager who needs to make a decision requiring an incremental quantification of risk (U.S. EPA 1998 p. 97). Likewise, an RQ does not provide the risk manager with an indication of uncertainty surrounding the risk estimation (ibid). Further, RQs cannot address some questions raised by risk managers which can be pivotal to major regulatory decision-making on the basis of ecological risk concerns:

- What is the magnitude of defined risk -- How big is it?
- What is the probability of the risk -- How likely is it to occur?
- How certain are you that an adverse effect will occur -- How sure are you?

As noted in the US EPA Ecological Risk Assessment Guidelines (U.S. EPA 1998, p.92), "If the risks are not sufficiently defined to support a management decision, risk managers may elect to proceed with another iteration of one or more phases of the risk assessment process."

Refined Risk Assessment Methods[1]

Ecological risk assessments may be refined in many ways, including deterministic and probabilistic methods. The newest method, and the one receiving widespread attention at the present time, is the probabilistic risk assessment. Probabilistic risk assessment is a general term for a risk assessment that uses probability distributions to characterize variability and/or uncertainty in risk estimates. In these risk assessments, one or more (random) variables in the risk equation are defined mathematically by probability distributions. Similarly, the output of a probabilistic risk assessment is a range or distribution of risks experienced by the various members of the exposed population of non-target organisms of concern. A risk assessment performed using probabilistic methods relies on the same fundamental concepts and equations as the traditional point estimate approaches.

In ecological risk assessments, risk distributions may reflect variability or uncertainty in exposure or toxicity. Following a deterministic screening level assessment that indicated potential high acute risk, a risk manager may request an answer to the following question: "What is the magnitude and likelihood (i.e., probability) of acute risks to an exposed individual

[1] Much of the discussion of probabilistic risk assessment methods was based on the following document: U.S. EPA. 1999. Risk Assessment Guidance for Superfund (RAGS): Volume 3, Part A, Process for conducting Probabilistic Risk Assessments. Draft.

from the use of Pesticide X?" After determining that the time, resources and expertise required to perform a probabilistic risk assessment was justified, the results of such an assessment could provide the following conclusion: *Based on the best available information regarding exposure and toxicity, mortality is expected to be 10% or greater in the majority (50% of more) of the scenarios, with a probability of 95%.* The above example is based on a situation where the available data permitted the development of distributions for both the toxicity and exposure variables. Other probabilistic results are possible when only one of the variables can be represented by a distribution.

An essential concept in PRA is the distinction between "variability" and "uncertainty". *Variability* refers to true heterogeneity or diversity. For example, among a population of birds that feeds in a field treated with a pesticide, the risks from consuming contaminated short grass, insects and seeds may vary. This may be due to differences in exposure (i.e., different birds consuming different amounts and kinds of food items, having different body weights, different exposure frequencies, and different exposure durations) as well as differences in response (e.g., genetic differences in resistance to a chemical dose). These inherent differences are referred to as *variability*. Differences among individuals in a population are referred to as inter-species variability, while differences for one individual over time is referred to as intra-species variability.

Uncertainty occurs because of a lack of knowledge. It is not the same as variability. For example, a risk assessor may be very certain that different birds consume different amounts of contaminated food, but may be uncertain about how much variability there is in food consumption within the population. Uncertainty can often be reduced by collecting more and better data, while variability is an inherent property of the population being evaluated. Variability can be better characterized with more data, but it cannot be reduced or eliminated. Efforts to clearly distinguish between variability and uncertainty are important for both risk assessment and risk communication.

The primary advantage of probabilistic risk assessment for assessing ecological risks within OPP is that it gives a quantitative description of the probability or likelihood of the impact as well as the magnitude or severity of the effect. The quantitative analysis of uncertainty and variability provides a more comprehensive characterization of risk than is possible in the deterministic RQ or point estimate method. Another significant advantage of probabilistic risk assessment is the additional information and potential flexibility it affords the risk manager. For example, the risk assessor can provide a range of percentile exposures (e.g., 5^{th}, 25th, 50^{th}, 75^{th}, 95^{th}) based on the distribution of these exposures, and the manager can select the percentile at which he/she is comfortable making a decision. Probabilistic risk assessment can also more reliably identify the variables and model parameters that have the greatest influence on the risk estimates through sensitivity analyses. Finally, once the probabilistic model is developed, it is relatively easy to modify the model to run "what-if" scenarios to determine the effect of mitigation measures on the risk conclusions.

While a probabilistic risk assessment can provide a useful tool to characterize and quantify variability and uncertainty in risk assessments, it is not appropriate for every site. It generally requires more time, resources, and expertise on the part of the assessor, reviewer, and risk manager than a point estimate risk assessment. In addition, communicating the results of a probabilistic risk assessment may be a challenge. If the additional information is unlikely to affect the risk management decision, then it may not be prudent to proceed with a probabilistic risk assessment. However, if there is a clear value added from performing this assessment, then the use of probabilistic risk assessment as a risk assessment tool generally should be considered despite the additional resources that may be needed. The decision to use probabilistic risk assessment methods is pesticide and use-specific and is based on the complexity of the problems due to the behavior of the pesticide and the quality and extent of site-specific data. EFED recommends a tiered approach to risk assessment so that the scope of the assessment matches the scope of the pesticide and use-specific problems being assessed.

The FIFRA Scientific Advisory Panel (SAP) (FIFRA Scientific Advisory Panel, 1996a and 1996b) recognized and generally reaffirmed the utility of the current assessment process and methods for screening. The Panel also indicated that OPP's methods were deterministic for assessing the effects of pesticides to non-target organisms and suggested moving to probabilistic assessments for the chemicals of concern. The Panel strongly encouraged OPP to develop and validate tools and methodologies to conduct probabilistic assessments of ecological risk, as the Panel believed that these methods were necessary in order to achieve an appropriate level of understanding of ecological risk to support major regulatory decision-making. In 1997 EFED returned to the SAP and provided it with an overview of EFED's plans to move forward to address the comments made during the May 1996 meeting. The SAP was extremely supportive of EFED's efforts and commended the Agency for its "proactive response" to the comments made during the May 1996 meeting and for its extensive outreach efforts (FIFRA Scientific Advisory Panel, 1997). In June 1997, OPP began an initiative to develop and validate tools and methodologies for conducting probabilistic assessments that address terrestrial and aquatic risk within the context of the FIFRA regulatory framework. Subsequently, EFED formed the Ecological Committee on FIFRA Risk Assessment Methods (ECOFRAM), which was divided into Aquatic and Terrestrial Workgroups. They were comprised of experts drawn from government agencies, academia, contract laboratories, environmental advocacy groups, and industry and were tasked with identifying and developing probabilistic tools and methods for terrestrial and aquatic assessments under the FIFRA regulatory framework. They were also asked to identify developmental information and validation needs to ensure that their approaches support an assessment process that is scientifically defensible.

ECOFRAM's conclusions and recommendations were summarized in the Draft Aquatic Workgroup Report (Ecological Committee on FIFRA Risk Assessment Methods, 1999a) and the Draft Terrestrial Workgroup Report (Ecological Committee on FIFRA Risk Assessment Methods, 1999b) which were completed in April 1999. In these reports, ECOFRAM provided a proposed framework for risk assessment refinement. This was based on a tiered approach which moves from simple deterministic assessments through probabilistic methods, to an issue-specific probabilistic assessment at the higher tiers. After completion of the ECOFRAM draft reports, the Agency held two workshops (June 22 - 24, 1999) to provide EPA with scientific peer review, comment, and discussion of the recommendations contained in the reports. In general, the workshop participants supported the basic approach described by ECOFRAM and concluded it was scientifically sound. They noted some general issues, such as the need for validation of models, describing uncertainty at each tier, the lack of addressing multiple stressors or multiple chemicals, and the need for case studies. They also provided numerous specific comments and suggestions.

Following ECOFRAM, EFED formed the Probabilistic Risk Assessment Implementation Team within EFED, which was charged with developing an implementation plan for OPP that incorporates probabilistic tools and methods for the evaluation of potential ecological risk from pesticide exposure. The reports originating out of the ECOFRAM initiative served as the basis for development of this EFED implementation plan for conducting probabilistic ecological risk assessments. The implementation plan, presented to the SAP in April of 2000, outlined a proposed general approach for assessing pesticide risks to birds and aquatic organisms, including the use of probabilistic tools in a tiered manner (actually four Levels of Refinement). During the following months, EFED developed pilot aquatic and terrestrial models as well as a 'generic case study' in order to demonstrate the models. The models and the case study were reviewed by the SAP in March 2001, and the Panel described the Agency's efforts as being at the forefront of conducting an ecological probabilistic risk assessment. The EFED Implementation Team is currently finalizing the models which will be used for Level 2 Probabilistic Risk Assessments. [Find information for all SAP meetings at http://www.epa.gov/scipoly/sap/2001/index.htm]

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Table 1.

Risk Presumptions for Terrestrial Animals

Risk Presumption	RQ	LOC
Birds		
Acute High Risk	EEC[1]/LC50 or LD50/sqft[2] or LD50/day[3]	0.5
Acute Restricted Use	EEC/LC50 or LD50/sqft or LD50/day (or LD50 < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC50 or LD50/sqft or LD50/day	0.1
Chronic Risk	EEC/NOEC	1
Wild Mammals		
Acute High Risk	EEC/LC50 or LD50/sqft or LD50/day	0.5
Acute Restricted Use	EEC/LC50 or LD50/sqft or LD50/day (or LD50 < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC50 or LD50/sqft or LD50/day	0.1
Chronic Risk	EEC/NOEC	1

[1] abbreviation for Estimated Environmental Concentration (ppm) on avian/mammalian food items

[2] mg/ft^2 / LD50 * wt. of bird

[3] mg of toxicant consumed/day / LD50 * wt. of bird

Risk Presumptions for Aquatic Animals

Risk Presumption	RQ	LOC
Acute High Risk	EEC[1]/LC50 or EC50	0.5
Acute Restricted Use	EEC/LC50 or EC50	0.1
Acute Endangered Species	EEC/LC50 or EC50	0.05
Chronic Risk	EEC/MATC or NOEC	1

[1] EEC = (ppm or ppb) in water

Risk Presumptions for Plants

Risk Presumption	RQ	LOC
	Terrestrial and Semi-Aquatic Plants	
Acute High Risk	EEC[1]/EC25	1
Acute Endangered Species	EEC/EC05 or NOEC	1
	Aquatic Plants	
Acute High Risk	EEC[2]/EC50	1
Acute Endangered Species	EEC/EC05 or NOEC	1

[1] EEC = lbs ai/A
[2] EEC = (ppb/ppm) in water